

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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IN RE SYNERGY PHARMACEUTICALS, INC.	:	
SECURITIES LITIGATION	:	MEMORANDUM DECISION AND ORDER
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	:	18-CV-873 (AMD) (VMS)
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ANN M. DONNELLY , United States District Judge:		

Before the Court is the motion of a group of defendants—Gary S. Jacob, Gary G. Gemignani, Marino Garcia and Troy Hamilton—to dismiss the Second Amended Complaint (“SAC”). The defendants were senior executives of Synergy Pharmaceuticals, Inc. (ECF No. 105 at ¶¶ 20-23.) For the reasons that follow, the motion is granted.¹

On February 8, 2018, David Lee commenced this securities class action against Synergy, Jacob and Gemignani, on behalf of himself and all others similarly situated. (ECF No. 1.) On March 2, 2018, Wendell Rose filed a complaint against Synergy, Jacob, Gemignani, Garcia and Hamilton. *Rose v. Synergy Pharm. Inc.*, No. 18-CV-1344 (E.D.N.Y. Mar. 2, 2018), ECF No. 1. This Court consolidated the actions on June 22, 2018.² (ECF No. 51.) On August 31, 2018, the lead plaintiffs filed an amended complaint (ECF No. 53), and the defendants moved to dismiss that complaint on December 6, 2018 (ECF No. 71). While the motion was pending, Synergy filed for bankruptcy, resulting in an automatic stay of the action. (ECF Nos. 74, 76.) On

¹ I heard oral argument on September 28, 2021.

² This Court appointed Michael Margulis, Joseph Buck, Joseph Badolato, Robert Tilton and Cross Country Media and Sourcing, Inc. as the lead plaintiffs and approved Faruqi & Faruqi, LLP and WeissLaw LLP as lead class counsel. (ECF No. 51.)

September 16, 2019, the Court denied the defendants' motion to dismiss as moot, and granted the plaintiffs leave to file a second amended complaint.³ (ECF No. 86.)

On November 30, 2020, the lead plaintiffs filed the SAC.⁴ (ECF No. 105.) In the SAC, the plaintiffs allege that between November 10, 2016 and November 13, 2017 (the "Class Period"), some defendants issued false and misleading statements about the side-effect profile of Trulance, a chronic idiopathic constipation ("CIC") treatment that Synergy developed and sold. (*Id.* at ¶¶ 1, 5-7.) The plaintiffs also allege that some defendants made false and misleading statements about a \$300 million loan that Synergy secured from the private equity firm CRG LP (the "CRG Loan"). (*Id.* at ¶¶ 8-9.) According to the SAC, the defendants' misstatements and omissions artificially inflated Synergy's stock price, causing the plaintiffs to suffer a loss after new information about Trulance and the CRG Loan was disclosed to the market. (*Id.* at ¶¶ 7, 9.) The plaintiffs claim that the defendants violated Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b), 78t(a), and Rule 10b-5, 17 C.F.R. § 240.10b-5. (*Id.* ¶ 15.)

The defendants move to dismiss, arguing that the plaintiffs have not alleged any actionable misstatements or omissions, that they did not sufficiently plead scienter, and, with respect to the Trulance allegations, that they did not plausibly allege loss causation. (*See* ECF No. 109.)

³ On November 20, 2019, Magistrate Judge Vera M. Scanlon consolidated two other actions into this action. (ECF No. 90); *see McMullen v. Hamilton et al.*, 19-CV-825 (E.D.N.Y. Feb. 11, 2019); *Weber v. Hamilton et al.*, 19-CV-1352 (E.D.N.Y. Mar. 7, 2019).

⁴ The lead plaintiffs removed Synergy as a defendant in the SAC.

BACKGROUND⁵

Synergy was a pharmaceutical company focused on the development of gastrointestinal therapies. (ECF No. 105 at ¶ 26.) Synergy developed and distributed plecanatide, a prescription medication for CIC, trademarked under the name Trulance. (*Id.* at ¶ 26.) The company filed for bankruptcy on December 12, 2018. (*Id.* at ¶ 111.)

I. Trulance’s Side-Effect Profile

During the Class Period, Trulance was Synergy’s sole commercial product. (*Id.* at ¶ 26.) The Food and Drug Administration (“FDA”) approved Trulance for treating CIC on January 19, 2017 (*id.*), and Synergy began distributing Trulance in March of 2017 (*id.* at ¶ 29). At the time, Trulance competed with two other CIC drugs: Linzess—the leading CIC drug—and Amitiza. (*Id.* at ¶¶ 28, 31.) Diarrhea was a common side-effect of all three drugs.⁶ (*Id.* at ¶¶ 30, 32, 33.) Synergy did not conduct any head-to-head trials to determine whether Trulance was superior to Linzess or Amitiza. (*Id.* at ¶ 45; *see also id.* at ¶¶ 40-42 (describing the FDA’s evidentiary requirement for comparative claims).)

a. Public Disclosures

During the Class Period, the defendants made various public statements about Trulance’s side-effect profile. On November 9, 2016, Synergy published a press release, which included the following statements:

Safety and Tolerability of Plecanatide in Patients with Chronic Idiopathic Constipation:
Long-term Evidence from an Open-Label Study

Data presented from the long-term open-label safety study showed plecanatide was associated with low adverse events and low discontinuation rates in patients with CIC

⁵ The facts are taken from the complaint, assumed to be true for purposes of this motion, and are read in the light most favorable to the plaintiffs. *See Kleinman v. Elan Corp.*, 706 F.3d 145, 152 (2d Cir. 2013).

⁶ Trulance’s clinical trials tracked only so-called “bothersome” diarrhea (ECF No. 105 at ¶ 30), while Linzess’s clinical trials tracked all diarrhea events (*id.* at ¶ 32).

who received plecanatide (3 mg or 6 mg) once-daily for up to 72 weeks. The most common adverse events were diarrhea (7.1%) and urinary tract infection (2.2%). The remainder of adverse events occurred in less than 2% of patients treated with plecanatide. Adverse events leading to discontinuation occurred in 5.3% of patients treated with plecanatide, with discontinuation due to diarrhea occurring in 3.1% of patients.

* * *

“We are laser-focused on our key strategic imperatives of product readiness, market and brand readiness and organizational readiness,” said Troy Hamilton, Executive Vice President and Chief Commercial Officer of Synergy Pharmaceuticals Inc. “Based on our extensive market research, advisory board meetings and interactions with payers, healthcare providers and patients to-date, we are very encouraged about the positive impact that plecanatide will have in the market place as a differentiated therapeutic option for patients with CIC. . . . We strongly believe that we have the right strategy and right team to successfully launch plecanatide and address the unmet needs of a growing GI market.”⁷

(*Id.* at ¶ 48.)

Around February 17, 2017, Health Monitor Network (“HMN”) published a “Guide to CIC” paid for by Synergy.⁸ (*Id.* at ¶ 51.) The Guide included this claim: “Now there’s a treatment that treats constipation without causing diarrhea.” (*Id.* at ¶ 52.) A Trulance advertisement on the next page reads, “Does managing your constipation come with compromise?” (*Id.*) It also included an image of “seven figures, with the far-left figure representing a stool by someone who is constipated and a far-right figure representing someone suffering from diarrhea,” and a “woman in the center depicting a person on Trulance.” (*Id.*) Allergan, Linzess’s co-marketer, challenged the claims in the Guide to CIC and other Synergy advertisements. (*Id.* at ¶ 53.) Jacob responded in an October 17, 2017 letter that “[w]e stand behind our advertising and promotional materials and activities,” and that the advertising and promotional materials were part of Synergy’s “on-going review.” (*Id.*)

⁷ The plaintiffs challenge the italicized and underlined statements as false and misleading.

⁸ In the bankruptcy proceeding, HMN filed a proof of claim against Synergy for “goods and services” provided. (ECF No. 105 at ¶ 51.)

As of March 10, 2017, Synergy's website advertised that patients "shouldn't have to go to extremes for [their] Chronic Idiopathic Constipation," that "diarrhea isn't the goal of constipation relief[,] [i]t's a compromise," and that "[d]iarrhea is not efficacy—It's time to address the age-old tradeoff in CIC. Now there's Trulance."⁹ (*Id.* at ¶¶ 56, 59.)

In a March 21, 2017 investor conference, Garcia stated in relevant part:

So very strong efficacy, clearly this is what patients are looking for. But it's not just about increasing bowel movements. Having unlimited bowel movements is not what patients are really looking for in terms of normal. What they are looking for is, of course, increased bowel movements, but also normal stool consistency, what they don't want is to be cycling constantly between the constipated hard stools, the painful hard stools or the diarrhea, the side effects they might suffer from some of the treatments they've been on in the past.

* * *

This campaign scored off the charts for both groups. So it's been a consistent in terms of the messaging, images and creative campaign aimed at both groups, at the patients and the healthcare providers, pharmacists, physicians, etc. And the whole point is that with chronic constipation, the trade-offs that patients have had to make, the extremes they've had to go from constipation or to diarrhea because of some of the medications they may have been on in the past, that they no longer have to make that trade-off. That Trulance provides the promise of being able to make patients feel like they are normal, right smack in the middle between the extremes.

(*Id.* at ¶ 61.)

At another investor conference on May 3, 2017, the following exchange occurred:

[Unidentified Analyst]: What arguments do your representatives use to convince leading health care providers to switch from linaclotide [Linzess] to plecanatide [Trulance]? And conversely, what arguments do Ironwood reps use to keep those leading HCPs prescribing linaclotide? And I have a couple more.

[Gary Jacob]: Thanks for the question. We're not going to obviously, dive into our message platform for competitive reasons, but as we both discussed and as I talked about when – with the one slide that looked at our profile and ingrained in kind of what we get from the label. Our discussions are based on pharmacology, the efficacy, the safety/tolerability and the dosing, the balance of that approach. And you probably see

⁹ Sometime prior to the filing of the first amended complaint on August 31, 2018, Synergy removed these statements from its website. (ECF No. 53 at ¶ 132; ECF No. 105 at ¶ 142.)

that in some of the other materials that we have in our campaign right now. So that's kind of what we're talking to. I can't really talk to the competition. I do know obviously they've been out there for long period of time and have had kind of a standard approach. But for us, we're focused on that balance between the pharmacology, the reason I believe, the efficacy, safety/tolerability and the dosing.

(*Id.* at ¶ 63.)

b. Stock Price Movement

During the Class Period, Synergy's stock price reached a high of \$7.15 per share on January 31, 2017. (*Id.* at ¶ 153.) On July 31, 2017, pharmacy benefits management company Express Scripts released its 2018 National Preferred Formulary,¹⁰ which included Linzess and Amitiza as preferred medications, but did not include Trulance. (*Id.* at ¶¶ 65, 155.) Following this release, Synergy's stock price fell \$0.18 per share to close at \$3.88. (*Id.*)

On August 9, 2017, Synergy published a slideshow presentation summarizing its second quarter results. (*Id.* at ¶ 74.) The presentation showed that the weekly growth rate in Trulance prescriptions had slowed, and "nearly flat-lined at 4.46%" in July. (*Id.* at ¶¶ 74, 156.) The next day, Synergy's stock price fell \$0.46 per share to close at \$3.07. (*Id.* at ¶ 156.) Synergy's third quarter presentation, published on November 9, 2017, showed a "dramatic slowdown" in Trulance prescriptions, and disclosed that each prescriber was writing fewer Trulance prescriptions. (*Id.* at ¶¶ 102, 157.) The next day, Synergy's stock price fell \$0.25 per share to close at \$2.72. (*Id.* at ¶ 157.)

c. Scienter Allegations

The plaintiffs make various factual allegations to support their claim that the defendants knowingly or recklessly defrauded investors on Trulance's side-effect profile. First, they say

¹⁰ The National Preferred Formulary "includes all clinically superior medications, but excludes me-too options that have no added clinical benefit but have higher costs." (ECF No. 105 at ¶ 67 (internal quotation marks and footnote omitted).)

that the defendants knew of “the evidentiary requirements imposed by the FDA for drug superiority claims,” and note Garcia’s acknowledgement that Synergy did not conduct “any head-to-head studies versus other competitors.” (*Id.* at ¶ 116.) The plaintiffs also say that some defendants knew of “Trulance’s and Linzess’[s] clinical data, including the fact that Trulance’s Phase 3 trial recorded incidents of diarrhea differently than Linzess’[s] trials.” (*Id.* at ¶ 118.) Further, Jacob and Synergy “declined to produce any information that would demonstrate compliance” in response to Allergan’s letter to the National Advertising Division of the Better Business Bureau (“NAD”) regarding Synergy’s “false and misleading advertising,” even though “any reasonable company confronted by such claims would have responded with evidence if they were not true.” (*Id.* at ¶¶ 119-120.) The defendants also “encouraged investors and analysts to view Synergy’s promotional materials”—such as “in-office print or displays,” “digital media and social media” campaigns, and Synergy’s “website”—while they conducted an “on-going review of these promotion materials.” (*Id.* at ¶¶ 121-22.)

In addition, the plaintiffs cite the defendants’ experience in the pharmaceutical industry (*id.* at ¶¶ 131-36), their motivation to “inflate Synergy’s stock price [artificially] because doing so allowed Synergy to obtain more cash via frequent public and private share offerings” (*id.* at ¶¶ 137-40), their failure to file the Guide to CIC with the FDA and the removal of “false and misleading content from [Synergy’s] website” (*id.* at ¶¶ 141-42), the “suspicious timing of Jacob’s sudden resignation” (*id.* at ¶ 147), and “the importance of Trulance” to the company (*id.* at ¶¶ 148-50).

II. CRG Loan

Prior to the Class Period, Synergy “determined to pursue a go-it-alone strategy to commercialize Trulance” without any partnerships, and needed “substantial capital” to do so.

(*Id.* at ¶¶ 77-78.) In February of 2017, the company completed a secondary offering of 20 million new shares at \$6.15 per share, diluting outstanding shares by more than 11%.¹¹ (*Id.* at ¶¶ 78, 137.) Later in 2017, Synergy entered into a \$300 million debt financing arrangement with CRG LP, which consisted of an initial funding of \$100 million, an additional \$100 million on or before February 28, 2018, and two additional tranches of \$50 million each on or before March 29, 2019. (*Id.* at ¶ 82.) Pursuant to the Term Loan Agreement’s “Cash Condition Precedent” provision, Synergy had to maintain at least \$128 million in cash or cash equivalents as of January 31, 2018 to obtain the second \$100 million in funding.¹² (*Id.* at ¶ 83.)

a. Public Disclosures

Synergy first disclosed the CRG Loan on September 5, 2017, when it issued a press release titled “Synergy Pharmaceuticals Secures \$300 Million Debt Financing,” which stated in relevant part:

Synergy Pharmaceuticals Inc. (NASDAQ: SGYP), announced today that the Company has closed on a \$300 million debt financing structured as senior secured loans from CRG LP, a healthcare focused investment firm, and its lender syndicate.

“This non-dilutive financing enhances our cash position and provides us with financial flexibility to continue to execute on the launch of Trulance and achieve our business objectives, which we are confident will ultimately maximize long-term shareholder value,” said Gary Gemignani, EVP and Chief Financial Officer of Synergy Pharmaceuticals Inc. *“The structure of this financing provides us with access to capital for support of our commercialization of Trulance and funds our current plans for the Company through 2019 when, based on our current assumptions, we expect to be cash flow breakeven.”*

(*Id.* at ¶ 89.)

¹¹ In addition, Synergy had privately exchanged shares for debt in three separate transactions in November of 2016. (ECF No. 105 at ¶ 137.)

¹² “Cash or cash equivalents” were “funds from operations or other sources of financing that do not include any proceeds of borrowings from any third party incurred after the date” of the agreement. (ECF No. 105 at ¶ 83.)

That same day, Synergy filed a Form 8-K, which included the following statements:

The Loan Agreement provides for a \$300.0 million term loan facility to the Company, \$100.0 million of which was borrowed at closing (the “Initial Term Loan”). The Loan Agreement provides for future borrowings, subject to the satisfaction of certain financial and revenue milestones and other borrowing conditions as follows: (i) an additional \$100.0 million on or before February 28, 2018 (the “Second Tranche Term Loan”), and (ii) up to two additional tranches of up to \$50.0 million each on or before March 29, 2019 (together with the Initial Term Loan and the Second Tranche Term Loan, the “Term Loans”).

* * *

In addition, the Loan Agreement requires the Company to comply with a minimum market capitalization covenant, maintain its status as a national exchange listed public company, a daily minimum liquidity covenant and an annual revenue requirement based on the sales of Trulance.

(*Id.* at ¶ 91.)

On September 7, 2017, Synergy hosted a conference call, and the defendants again emphasized the “non-dilutive” nature of the financing, the resulting “financial flexibility,” and that the CRG Loan would fund Synergy’s plans through 2019. (*Id.* at ¶ 95.) Jacob stated that the CRG Loan provided “access to additional capital if and when we need it.” (*Id.*) Gemignani also said that “as we constructed the tiers, we’re very comfortable we’ll be able to meet all of the commitments.” (*Id.*) Gemignani made similar statements during Synergy’s November 9, 2017 Q3 earnings call. (*Id.* at ¶ 100.) The Term Loan Agreement was publicly filed on that same day, November 9, 2017, as part of Synergy’s Q3 2017 Form 10-Q. (*Id.* at ¶¶ 83, 146; ECF No. 110-19 at 5-90.)

b. Stock Price Movement

On November 13, 2017, Synergy announced a \$56 million stock offering. (*Id.* at ¶¶ 104, 159.) Synergy’s share price fell \$0.28 per share to close at \$2.44 per share. (*Id.* at ¶ 159.) The next day, Synergy “revealed the existence of the Cash Condition Precedent, that the funds from the CRG Loan would not be available if and when needed, that the CRG Loan was not sufficient

to fund the commercialization of Trulance through 2019, that Synergy could not draw upon the Loan when it chose to do so, and that it would be necessary to launch a dilutive equity offering to meet the Cash Condition Precedent's terms and access the remaining portions of the funding.”¹³ (*Id.* at ¶ 160.) Synergy's share price fell another \$0.41 per share to close at \$2.03. (*Id.*)

c. Scierter Allegations

The plaintiffs allege that the defendants knew about the structure and terms of the CRG Loan because Gemignani signed the Term Loan Agreement on Synergy's behalf and made public statements about the “structure” of the loan, Jacob approved the loan as a member of Synergy's board of directors, and the company's September 5, 2017 Form 8-K disclosing the CRG Loan “discusse[d] various covenants and requirements contained in the Loan.” (*Id.* at ¶¶ 124-127.) The defendants were also allegedly aware of the company's financial state, including its “cash position,” “cash burn rate,” and that “the \$128 million Cash Condition Precedent all but necessitated a dilutive equity offering.” (*Id.* at ¶¶ 128-30.) The plaintiffs note that Jacob and Gemignani “signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (‘SOX’)” in connection with Synergy's SEC filings. (*Id.* at ¶¶ 145-46.)

In addition, the plaintiffs claim that the defendants “initially concealed the Cash Condition Precedent from investors” in order to buy “time to dilute [Synergy's] shareholders via a \$56 million public offering” days later. (*Id.* at ¶¶ 143-44.) They also cite the defendants' financial experience (*id.* at ¶¶ 131-36), the timing of Jacob's resignation (*id.* at ¶ 147), and the importance of Trulance to the company (*id.* at ¶¶ 148-50).

¹³ The plaintiffs cite two third-party reports dated November 14, 2017—one that called the public offering a “surprise,” and another that described Synergy's disclosures regarding the CRG Loan as “obfuscation in hindsight, bordering on deliberate misdirection.” (ECF No. 105 at ¶¶ 106-07.)

The plaintiffs, on behalf of a putative class, claim that the defendants committed securities fraud in violation of Section 10(b) of the Securities Exchange Act of 1934 and its implementing regulation, Rule 10b-5, because they made false and misleading statements about Trulance's side-effect profile and the CRG Loan (Count I). (*Id.* at ¶¶ 181-91.) They also claim that the defendants are liable under Section 20(a) of the Exchange Act as controlling persons of Synergy with the power to direct activities that comprised the securities violations (Count II). (*Id.* at ¶¶ 192-97.) On January 28, 2021, the defendants moved for dismissal, arguing that the plaintiffs did not adequately plead the existence of false or misleading statements, the required "strong inference" of scienter, or, with respect to the Trulance-related allegations, loss causation. (*See* ECF Nos. 108 & 109.) As explained below, that motion is granted.

DISCUSSION

In order to survive a motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In a securities fraud case, the court may consider "any written instrument attached to the complaint as an exhibit or any statements or documents incorporated in it by reference, as well as public disclosure documents required by law to be, and that have been, filed with the [SEC], and documents that the plaintiffs either possessed or knew about and upon which they relied in bringing the suit." *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 100 (2d Cir. 2015) (internal alterations and citation omitted).

A plaintiff alleging securities fraud must comply with the heightened pleading requirements detailed in Rule 9(b) of the Federal Rules of Civil Procedure and the Private

Securities Litigation Reform Act of 1995 (the “PSLRA”), 15 U.S.C. § 78u–4(b). *See ATSI Commc’ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007) (affirming that securities fraud claims must satisfy the heightened pleading standards of both Rule 9(b) and the PSLRA); *In re Sterling Foster & Co., Inc., Sec. Litig.*, 222 F. Supp. 2d 216, 269 (E.D.N.Y. 2002) (noting that the PSLRA was intended to make the “pleading requirements for securities fraud cases more demanding”). Under Rule 9(b), a plaintiff must “state with particularity the circumstances constituting fraud.” Fed. R. Civ. P. 9(b). “[T]o satisfy this requirement the plaintiff must ‘(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.’” *Anschutz Corp. v. Merrill Lynch & Co.*, 690 F.3d 98, 108 (2d Cir. 2012) (quoting *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004)). Under the PSLRA, a securities fraud plaintiff must “specify each misleading statement,” explain why the statement is misleading, and “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” *Id.* (citing *Dura Pharms., Inc v. Broudo*, 544 U.S. 336, 345 (2005)) (internal quotation marks and alterations omitted); *see also* 15 U.S.C. § 78u–4(b)(1), (2).

I. Section 10(b) Claim

“Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful to ‘use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of [the] rules and regulations’ that the SEC prescribes.” *Stratte-McClure*, 776 F.3d at 100 (citing 15 U.S.C. § 78j); *see also* 17 C.F.R. § 240.10b-5. To sustain claims under Section 10(b) or Rule 10b-5, a complaint must plausibly allege: “(1) a material misrepresentation (or omission); (2) scienter, i.e., a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance . . . ; (5) economic

loss; and (6) loss causation.” *Singh v. Cigna Corp.*, 918 F.3d 57, 62 (2d Cir. 2019) (quoting *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 152 (2d Cir. 2013)) (internal quotation marks and brackets omitted).

The plaintiffs’ allegations of misleading statements or omissions fall into two categories: (i) statements about Trulance’s side-effect profile, and (ii) statements about the CRG Loan.

a. Trulance’s Side-Effect Profile

The plaintiffs fault some of the defendants for making false and misleading statements about Trulance’s side-effect profile; the plaintiffs say that the defendants touted Trulance’s superior side-effect profile, and compared it to its competitors.¹⁴ The defendants argue that the plaintiffs have not alleged that they made false or misleading statements about Trulance’s side-effect profile, a causal connection between the alleged false statements and losses, or facts giving rise to a strong inference of scienter.

i. Material Misrepresentations or Omissions

The plaintiffs maintain that the defendants led investors to believe that Trulance had a superior side-effect profile by making the following statements or representations: calling Trulance a “differentiated therapeutic option” (ECF No. 105 at ¶ 48), advertising that patients who took Trulance would not have to “compromise” (*id.* at ¶¶ 52, 56, 59), stating that patients would not experience a “trade-off” with Trulance unlike “some of the medications [patients] may

¹⁴ The plaintiffs do not allege that Gemignani made any misstatements about Trulance’s side effects.

have been on in the past” (*id.* at ¶ 61), and highlighting “safety/tolerability” as a reason to switch to Trulance (*id.* at ¶ 63).¹⁵

To establish falsity, plaintiffs must do more than simply assert that a statement is false; “they must demonstrate with specificity why that is so.” *Rombach*, 355 F.3d at 174. “A violation of Section 10(b) and Rule 10b-5 premised on misstatements cannot occur unless an alleged material misstatement was false at the time it was made.” *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014) (citing *San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos., Inc.*, 75 F.3d 801, 812-13 (2d Cir. 1996)), *aff’d*, 604 F. App’x 62 (2d Cir. 2015).

The plaintiffs cite multiple statements that do not appear to be comparative statements about Trulance’s side-effect profile. For instance, the plaintiffs do not explain how the description of Trulance as a “differentiated therapeutic option” conveyed that Trulance’s side-effect profile was superior to other brands, as opposed to other differentiating features. Further, the references to “safety/tolerability”—that Synergy’s “discussions [with healthcare providers] are based on pharmacology, the efficacy, the safety/tolerability and the dosing, the balance of that approach” (ECF No. 105. at ¶ 63)—make no comparisons, and are part of statements that cite other factors. Read in context, the defendants did not say that Trulance’s side-effect profile

¹⁵ Although the earlier complaint does not include the FDA-related allegations, it does include many of the purportedly false statements alleged in the SAC. *See Rose*, No. 18-CV-1344, ECF No. 1 at ¶¶ 28, 30, 31. Co-lead counsel previously argued—in the context of arguments about lead plaintiff appointment—that no allegation “plausibly support[s] the assertion that Trulance’s side-effect profile representations during the expanded class period were materially false and misleading.” (ECF No. 26 at 12-13.)

was superior to other brands, but rather that all of Trulance’s characteristics, considered together, made it a desirable medication.¹⁶

Nor have the plaintiffs demonstrated “with specificity” that the statements were “actually false or misleading.” *Rombach*, 355 F.3d at 172, 174. Since the plaintiffs claim that the statements were false or misleading, they must allege that Trulance’s side-effect profile was not in fact superior. See *Lululemon*, 14 F. Supp. 3d at 577 (“That is, lead plaintiff must allege that [L]ululemon's product quality was not ‘superior,’ that the company was not a ‘leader in technical fabrics and quality construction,’ that the company did not ‘deliver quality,’ and so forth.”). While the plaintiffs allege that “Trulance does not have a superior side-effect profile to its competitors, including with respect to diarrhea” (e.g., ECF No. 105 at ¶¶ 49(a), 54(b), 56(a), 60(a), 62(a), 64(b)), they cite the SAC claims about Trulance’s Phase 3 trials (*id.* at ¶ 30), Linzess’s Phase 3 trials (*id.* at ¶ 32), the FDA’s evidentiary requirements for comparative claims (*id.* at ¶¶ 40-42), and the fact that Synergy did not conduct head-to-head trials and that Trulance’s trials were different than Linzess’s trials (*id.* at ¶¶ 45-46).

None of these allegations establish that the defendants’ statements were false. While the purportedly false statements—especially those that explicitly refer to “medications” or “treatments” patients may have taken in the past—suggest that Trulance’s side-effect profile was superior to its competition’s, they do not include any statements about studies or trials. Moreover, the plaintiffs’ reliance on the FDA’s guidance and rules is misplaced. The FDA requirements quoted in the SAC come from the agency’s “Guidance for Industry, Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products” and

¹⁶ The plaintiffs also refer to this statement purportedly about Trulance in the Guide to CIC: “Now there’s a treatment that treats constipation without causing diarrhea.” (ECF No. 105 at ¶ 52; ECF No. 105-2 at 9.) However, the Trulance advertisement on the next page says in bold text that “[d]iarrhea is the most common side effect and can sometimes be severe.” (ECF No. 105-2 at 10.)

“Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products,” both of which apply to prescription drug labels, not public statements at issue here. Accordingly, even assuming that the FDA were to determine that the defendants’ statements—which were not on Trulance’s label—were not substantiated by head-to-head trials, that determination is irrelevant in the context of this securities fraud action. The plaintiffs have not alleged any specific facts that contradict the defendants’ statements. Accordingly, the plaintiffs have not adequately alleged material misstatements or omissions about Trulance’s side-effect profile.¹⁷

ii. Loss Causation

Although I conclude that the plaintiffs have not alleged actionable statements or omissions, I also address whether they have sufficiently pled loss causation. The plaintiffs claim that three events each partially corrected the defendants’ allegedly false statements regarding Trulance’s superior side-effect profile. First, “on July 31, 2017, Express Scripts published its 2018 National Preferred Formulary, which excluded Trulance but included Linzess and Amitiza.” (*Id.* at ¶ 155.) Second, on August 9, 2017, Synergy disclosed that the growth rate in Trulance prescriptions had “nearly flat-lined.” (*Id.* at ¶ 156.) Third, on November 9, 2017, the company further disclosed that “individual prescribers were writing fewer Trulance prescriptions.” (*Id.* at ¶ 157.)

“Loss causation . . . is the proximate causal link between the alleged misconduct and the plaintiff’s economic harm.” *ATSI Commc’ns*, 493 F.3d 87 at 106. A plaintiff establishes loss causation by alleging that “the *subject* of the fraudulent statement or omission was the cause of the actual loss suffered, *i.e.*, that the misstatement or omission concealed something from the

¹⁷ Since the plaintiffs have not demonstrated the defendants’ statements are false or misleading, I do not address whether statements in the Guide to CIC could be attributed to the defendants.

market that, when disclosed, negatively affected the value of the security.” *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173 (2d Cir. 2005) (internal citation omitted). Accordingly, the plaintiff must show “both that the loss be foreseeable *and* that the loss be caused by the materialization of the concealed risk.” *Id.*

The plaintiffs allege that Express Scripts’ National Preferred Formulary “includes ‘all clinically superior medications,’ but excludes ‘me-too options that have no added clinical benefit but have higher costs.’” (ECF No. 105 at ¶ 67.) Accordingly, they conclude that the exclusion of Trulance from the 2018 National Preferred Formulary meant that Express Scripts determined that Trulance’s side-effect profile was not “in fact superior to its competitors.” (*Id.* at ¶ 70.) However, the plaintiff alleges no facts about how Express Scripts determines whether a drug is “clinically superior,” or whether Express Scripts considered Trulance’s side-effect profile when it excluded Trulance from the Formulary. Because “[t]he number of dots the Court must connect to produce an adequate theory of loss causation are too numerous and attenuated to succeed,” *Lululemon*, 14 F. Supp. 3d at 587, I find that the plaintiffs have not alleged loss causation with respect to the release of the 2018 Formulary.

Synergy’s disclosures about the weakening growth rate in Trulance prescriptions are even more tenuous. The plaintiffs do not explain how these disclosures “relate back to” the defendants’ alleged misrepresentations about Trulance’s side-effect profile. *Solow v. Citigroup, Inc.*, No. 10-CV-2927, 2012 WL 1813277, at *9 (S.D.N.Y. May 18, 2012), *aff’d*, 507 F. App’x 81 (2d Cir. 2013) (“Rather than relate back to Defendants’ alleged misrepresentations, the events and dates Plaintiff identifies relate to other negative information about the company, thereby insufficiently establishing loss causation.”). There are no facts alleged connecting the declining growth in prescriptions to Trulance’s side-effect profile; “[s]uch a decline might be the result of

a market-wide downturn, an industry-specific phenomenon, or other intervening events unrelated to the disclosure defect at issue.” *In re Bristol Myers Squibb Co. Sec. Litig.*, 586 F. Supp. 2d 148, 163 (S.D.N.Y. 2008). Accordingly, I find that the plaintiffs have not adequately alleged loss causation based on these quarterly disclosures.¹⁸

b. CRG Loan

The plaintiffs claim the defendants made false and misleading statements about the CRG Loan when it was announced on September 5, 2017 and in investor calls.¹⁹ The defendants respond that the plaintiffs have not adequately alleged any material misstatement or omission, or any facts giving rise to a strong inference of scienter.

i. Material Misrepresentations or Omissions

The plaintiffs fault the defendants for describing the CRG Loan on multiple occasions as “non-dilutive” financing that “provides” the company access to additional capital “if and when” needed. (ECF No. 105 at ¶¶ 89, 95, 100.) They argue that this description is misleading because the “Cash Condition Precedent required Synergy to have \$128 million in cash or cash equivalents as of January 31, 2018 in order to obtain the second tranche of \$100 million in financing,” and given “Synergy’s available cash, cash-burn rate, and Trulance revenues,” “the CRG Loan could not be accurately described as ‘non-dilutive’ without meaningful disclosure of the highly material Cash Condition Precedent, which all but necessitated that Synergy conduct another dilutive secondary offering of shares.” (*Id.* at ¶ 90.) Synergy announced a \$56 million

¹⁸ Because the plaintiffs have not adequately pled that the defendants made false or misleading statements, nor loss causation, I do not address scienter.

¹⁹ The plaintiffs do not allege that Garcia made any misstatements about the CRG Loan.

secondary offering on November 13, 2017, approximately two months after it first disclosed the CRG Loan. (*Id.* at ¶¶ 104, 159.)

“Similar to the falsity of statements, omissions are only actionable if a defendant is under a duty to disclose information and fails to do so.” *Lululemon*, 14 F. Supp. 3d at 571-72 (citing *Levitt v. J.P. Morgan Sec., Inc.*, 710 F.3d 454, 465 (2d Cir. 2013)). However, when a company decides to disclose certain information, “[d]isclosure is required . . . to make . . . the statements made, in the light of the circumstances under which they were made, not misleading.” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011) (internal quotation marks omitted) (quoting Rule 10b–5, 17 C.F.R. § 240.10b–5(b)); see *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 239 (2d Cir. 2016). In other words, “once a company speaks on an issue or topic, there is a duty to tell the whole truth, even where there is no existing independent duty to disclose information on the issue or topic.” *Vivendi*, 838 F.3d at 258 (internal quotation marks omitted); see *Caiola v. Citibank, N.A., N.Y.*, 295 F.3d 312, 331 (2d Cir. 2002) (when a party chooses to speak on a subject, it has a “duty to be both accurate and complete”). A statement or omission is material when there is “a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available” to the market. *IBEW Local Union No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scot. Grp., P.L.C.*, 783 F.3d 383, 390 (2d Cir. 2015) (internal quotation marks and citations omitted).

Here, the defendants told investors that the CRG Loan was non-dilutive—including by describing the additional tranches as “up to an additional \$200 million in non-dilutive capital”—

and provided capital if and when it was needed.²⁰ (ECF No. 105 at ¶ 100.) These statements, taken together, could mislead a reasonable investor to believe that the CRG Loan was structured such that Synergy had ready, unfettered access to additional financing. Synergy did not disclose, however, that the company had to satisfy a \$128 million cash requirement to obtain any additional financing. In light of the company's cash balance and expenses during the relevant time period, and the magnitude of the cash requirement, a reasonable investor would have considered that the Cash Condition Precedent significantly altered the total mix of information.²¹ If investors knew about the Cash Condition Precedent, they would know that Synergy might struggle to obtain additional tranches of financing, and that the company may have to pursue additional stock offerings or other strategies to meet the cash requirement.²² Accordingly, the

²⁰ The defendants contend, and the plaintiffs do not dispute, that certain general statements describing the CRG Loan's structure and the company's plans for using the financing are true. (ECF No. 109 at 40-41.)

²¹ Synergy reported \$82 million of cash and \$73.6 million of expenses for Q2 2017, and \$117.8 million in cash and \$47.7 million of expenses for Q3 2017. (ECF No. 105 at ¶¶ 72, 85.) The latter cash amount presumably incorporated the \$100 million upfront financing provided by the CRG Loan.

²² As noted previously, third-party borrowing proceeds do not count towards the cash requirement. (ECF No. 105 at ¶ 83.)

plaintiffs have adequately alleged that this omission of information regarding the CRG Loan was materially misleading.²³

The defendants argue that the following statements are not actionable because they are forward-looking, statements of opinion, or puffery:

- “[W]e are confident [that using the CRG Loan to support Trulance’s launch and Synergy’s business objectives] will ultimately maximize long-term shareholder value.”
- The CRG Loan “funds our current plans for the Company through 2019 when, based on our current assumptions, we expect to be cash flow breakeven.”
- “[W]e are confident in our ability to meet all of the performance milestones stated under the terms of [the CRG Loan] agreement, and we will have access to additional capital if and when we need it.”
- “[A]s we constructed the tiers [of the CRG Loan], we’re very comfortable we’ll be able to meet all of the commitments.”
- “[W]e are confident in our ability to meet the conditions that will allow us to access . . . the additional capital if and when we need it.”

(ECF No. 109 at 41-42; ECF No. 105 at ¶¶ 89, 95, 100.)

Puffery includes “vague and optimistic ‘statements [that] are too general to cause a reasonable investor to rely upon them,’ and thus cannot serve as the basis for a securities fraud claim.” *Steamfitters’ Indus. Pension Fund v. Endo Int’l PLC*, 771 F. App’x 494, 497 (2d Cir.

²³ I am not persuaded that the company disclosed the Cash Condition Precedent “in substance” when it referred to “the satisfaction of certain financial and revenue milestones and other borrowing conditions” (ECF No. 105 at ¶ 91), or warned of the potential “need for additional financing” and other “risks and uncertainties”. (ECF No. 109 at 39.) These generic and vague disclaimers and warnings do not reveal the existence nor the extent of the \$128 million cash requirement. *See In re SunEdison, Inc. Sec. Litig.*, 300 F. Supp. 3d 444, 473 (S.D.N.Y. 2018) (finding that the descriptions of certain collateral requirements were “opaque” when a reasonable investor could not determine whether the value of collateral “may have been minimal and immaterial, or they may have been substantial”).

Ross v. Lloyds Banking Grp., PLC, upon which the defendants rely, is distinguishable. No. 11-CV-8530, 2012 WL 4891759 (S.D.N.Y. Oct. 16, 2012). In that case, the plaintiff alleged that the non-disclosure of a specific form of government funding was misleading, specifically because disclosure would have revealed a company’s “struggling conditions.” *Id.* at *9. The court determined that since the company had already disclosed “the necessity of government funding and acknowledged the adverse effect on their solvency if the funding became unavailable,” disclosure of the specific government funding would not have “materially altered the total mix of information.” *Id.* Here, the defendants did not disclose the existence of any significant cash requirement, or acknowledge the risks if Synergy did not satisfy the cash requirement.

2019) (summary order) (quoting *ECA, Local 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 206 (2d Cir. 2009)); see *Rombach*, 355 F.3d at 174 (“[E]xpressions of puffery and corporate optimism do not give rise to securities violations.”). I find that the first statement—that the CRG Loan “will ultimately maximize long-term shareholder value”—is too vague to be actionable.

The PSLRA provides a “safe-harbor for forward-looking statements.” *Slayton v. Am. Express Co.*, 604 F.3d 758, 765 (2d Cir. 2010). A forward-looking statement is “(i) identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement; or (ii) immaterial.” 15 U.S.C. § 78u-5(c). Forward-looking statements include statements “containing a projection of . . . income (including income loss), earnings (including earnings loss) per share, . . . or other financial items” and statements “of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management.” *Vivendi*, 838 F.3d at 246 (quoting *Slayton*, 604 F.3d at 766-67) (internal quotation marks omitted). “A statement may contain some elements that look forward and others that do not, and forward-looking elements may be severable from non-forward-looking elements.” *Vivendi*, 838 F.3d at 246. Meaningful cautionary statements “must convey substantive information about factors that realistically could cause results to differ materially from those projected in the forward-looking statement,” and “not merely a boilerplate litany of generally applicable risk factors.” *Slayton*, 604 F.3d at 771-72 (citations omitted).

The “critical portions” of the second statement—that the CRG Loan “funds our current plans for the Company through 2019”—is “phrased in the present tense,” and is a statement of

present fact.²⁴ *Cheng v. Canada Goose Holdings Inc.*, No. 19-CV-8204, 2021 WL 3077469, at *7 (S.D.N.Y. July 19, 2021). This statement, together with the descriptions of the CRG Loan as “non-dilutive” and providing access to capital “if and when” needed, could mislead a reasonable investor for the same reasons explained above, and is therefore actionable.

The remaining three statements pertain to the company’s ability “to meet” the milestones and conditions of the CRG Loan. While the defendants used the terms “confident” and “comfortable,” these statements “merely endorse or state the speaker’s belief in a certain future outlook,” which “satisf[ies] the PSLRA forward-looking requirement.” *Gray v. Wesco Aircraft Holdings, Inc.*, 454 F. Supp. 3d 366, 387 (S.D.N.Y. 2020), *aff’d*, 847 F. App’x 35 (2d Cir. 2021); *see also Institutional Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 254-56 (3d Cir. 2009) (holding that the statement, “Our first quarter results position us to meet our goals for the year,” was forward looking).

The defendants argue that the forward-looking statements were accompanied by meaningful cautionary language, including risk disclosures regarding the company’s “need for additional financing,” “ability to fund the payment of interest and principal of the loan amounts and to continue as a going concern,” and “the risk that we are unable to manage our operating expenses or cash use for operations.” (ECF No. 109 at 42.) They concede that the “additional financing” and “cash use” cautionary statements remained the same before and during the Class Period.²⁵ (ECF No. 119 at 22 n.18); *see In re Salix Pharms., Ltd.*, No. 14-CV-8925, 2016 WL

²⁴ Though the defendants characterized all the statements as “statements of opinion,” the quoted portion of this statement is clearly not one.

²⁵ The defendants seem to concede that there were no changes made to the cautionary statements except for the addition of the “ability to fund the payment of interest and principal of the loan amounts and to continue as a going concern.” (ECF No. 119 at 22 n.18.) That factor is not related to the company’s ability to meet the Cash Condition Precedent.

1629341, at *12 (S.D.N.Y. Apr. 22, 2016) (“Defendants’ failure to update these statements [with respect to inventory] from quarter to quarter and from year to year renders them meaningless in light of the changing circumstances and risks.”). Not only did the defendants not update these disclaimers, the disclaimers “failed to link any specific projections to specific risks”—that the company’s ability to meet a condition of the CRG Loan depended on the company’s cash balance, and that the company could initiate additional stock offerings to meet the condition. *Sgalambo v. McKenzie*, 739 F. Supp. 2d 453, 478 (S.D.N.Y. 2010); *see also In re Skechers USA, Inc. Sec. Litig.*, 444 F. Supp. 3d 498, 514 (S.D.N.Y. 2020) (finding that the cited cautionary statements were insufficient when the statements “do not address the specific risk” at issue, and “discuss the risks . . . only in general terms that do not provide sufficiently meaningful information” about the specific risk). Accordingly, the defendants’ statements are not covered by the PSLRA safe harbor for forward-looking statements.

Statements of opinion are actionable “if either ‘the speaker did not hold the belief she professed’ or ‘the supporting fact she supplied were untrue,’ or ‘the speaker omits information whose omission makes the statement misleading to a reasonable investor.’” *Tongue v. Sanofi*, 816 F.3d 199, 210 (2d Cir. 2016) (*quoting Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 194 (2015)). Though the remaining three statements regarding the company’s ability to meet the CRG Loan’s conditions are statements of opinion, they are, taken together with the other actionable statements about the CRG Loan, misleading for the reasons explained above, and are actionable.

ii. Scier

Though the plaintiffs have adequately alleged actionable statements or omissions, they have not sufficiently pled scier. To sustain a Section 10(b) or Rule 10b-5 action, the plaintiffs

must allege that each defendant acted with scienter—“a mental state embracing intent to deceive, manipulate, or defraud” investors. *Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 F. App’x 32, 38 (2d Cir. 2012) (quoting *Matrixx Initiatives*, 563 U.S. 27 at 46). The plaintiffs must “allege facts that give rise to a strong inference of fraudulent intent,” *Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 52 (2d Cir. 1995); a “strong inference” of scienter means an inference that is “cogent and at least as compelling as any opposing inference one could draw from the facts alleged.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). In addition, the “[p]laintiffs must allege those facts that give rise to an inference of scienter ‘with particularity.’” *Singh*, 918 F.3d at 62 (quoting *ATSI Commc’ns*, 493 F.3d at 99).

The plaintiffs may plead scienter in two ways: by alleging facts “(1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness.” *In re Magnum Hunter Res. Corp. Sec. Litig.*, 616 F. App’x 442, 445 (2d Cir. 2015) (citation omitted); *see also Boca Raton*, 506 F. App’x at 38 (citing *In re Carter–Wallace, Inc., Sec. Litig.*, 220 F.3d 36, 39 (2d Cir. 2000)). When the defendant is a corporation, a plaintiff must plead scienter with respect to “someone whose intent could be imputed to the corporation.” *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 195 (2d Cir. 2008).

To allege scienter under the “motive and opportunity” theory, a plaintiff must show that the defendant “benefitted in some concrete and personal way from the purported fraud.” *Woolgar v. Kingstone Cos., Inc.*, 2020 WL 4586792, at *21 (S.D.N.Y. Aug. 10, 2020). Ordinarily, a plaintiff establishes motive by alleging that “corporate insiders are alleged to have misrepresented to the public material facts about the corporation’s performance or prospects in order to keep the stock price artificially high while they sold their own shares at a profit.” *S.*

Cherry St., LLC v. Hennessee Grp. LLC, 573 F.3d 98, 108 (2d Cir. 2009). The plaintiffs do not allege that the defendants made any stock trades during the Class Period, or personally profited. Instead, they argue that the defendants “concealed the Cash Condition Precedent” in order to buy “time to dilute [Synergy’s] shareholders via a \$56 million public offering, diluting shareholder interests by about 10%, announced” on November 13, 2017. (ECF No. 105 at ¶¶ 143-44.) They further explain that the defendants “had ample motivation to conceal material information from the market that they knew would lower [the] trading price prior to a share offering upon which the Company’s future depended.” (ECF No. 114 at 53.) However, Synergy advised in its September 5, 2017 Form 8-K announcing the CRG Loan that the “description of the Loan Agreement” in the 8-K “is not intended to be complete and is qualified in its entirety by reference to the Loan Agreement, copies of which will be filed . . . [in the] Form 10-Q” for the third quarter of 2017. (ECF No. 110-20 at 3.) The plaintiffs acknowledge that Synergy publicly filed the entire Term Loan Agreement, including the Cash Condition Precedent, on November 9, 2017.²⁶ (ECF No. 105 at ¶ 146.) Since the defendants told investors that the loan agreement would be publicly filed in the Form 10-Q, and disclosed the Cash Condition Precedent before the announcement of the public offering, the plaintiffs’ allegations do not raise a strong inference of fraudulent intent.²⁷ On the contrary, it is hard to believe that the defendants would disclose the entire loan agreement prior to the stock offering announcement if they intended to defraud investors.

²⁶ During a June 12, 2018 status conference before Judge Scanlon, co-lead counsel argued that disclosure of the entire loan agreement on November 9, 2017 was a “meaningful corrective disclosure,” and an investor cannot “rel[y] on false statements about the loan agreement when the loan agreement was already public.” (ECF No. 48 at 22-24.)

²⁷ Notably, the plaintiffs allege that “the market for Synergy’s securities was an efficient market” and “promptly digested current information with respect to the Company from all publicly available sources.” (ECF No. 105 at ¶ 172.)

Nor have the plaintiffs alleged enough facts to show conscious misbehavior or recklessness. “Conscious misbehavior or recklessness” is a “state of mind ‘approximating actual intent,’ which can be established by ‘conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.’” *City of Pontiac Policemen’s & Firemen’s Ret. Sys. v. UBS AG*, 752 F.3d 173, 184 (2d Cir. 2014) (citation omitted); *see S. Cherry*, 573 F.3d at 109 (To establish “conscious recklessness,” the plaintiff must establish that the defendants had “a state of mind approximating actual intent, and not merely a heightened form of negligence.” (citing *Novak v. Kasaks*, 216 F.3d 300, 312 (2d Cir. 2000)) (internal quotation marks omitted)). For this reason, “an allegation that a defendant merely ‘ought to have known’ is not sufficient to allege recklessness.” *Hart v. Internet Wire, Inc.*, 145 F. Supp. 2d 360, 368 (S.D.N.Y. 2001) (citation omitted). Where a plaintiff cannot make a showing of “motive,” the “strength of the circumstantial allegations must be correspondingly greater.” *ECA*, 553 F.3d at 198-99 (quotation marks and citation omitted).

A plaintiff can establish “conscious recklessness” by alleging that the defendants “knew facts or had access to information suggesting that their public statements were not accurate.” *Emps.’ Ret. Sys. of Gov’t of the Virgin Islands v. Blanford*, 794 F.3d 297, 306 (2d Cir. 2015) (quotation marks and citations omitted); *see also Novak*, 216 F.3d at 308 (The plaintiff must have “specifically alleged defendants’ knowledge of facts or access to information contradicting their public statements.”); *In re Marsh & McLennan Cos., Inc. Sec. Litig.*, 501 F. Supp. 2d 452, 484 (S.D.N.Y. 2006) (The plaintiff must plead “that specific contradictory information was available to the defendants at the same time they made their statements.”). Further, “[w]here plaintiffs contend defendants had access to contrary facts, they must specifically identify the

reports or statements containing this information.” *Teamsters*, 531 F.3d at 196-97 (quotation marks and citation omitted); *see also Tyler v. Liz Claiborne, Inc.*, 814 F. Supp. 2d 323, 336-37 (S.D.N.Y. 2011) (“[S]pecific identification of reports or other documents indicating defendants’ recklessness as to their public statements’ truth or falsity suggests an inference of scienter strong enough to survive a motion to dismiss.”).

The plaintiffs allege that Gemignani “signed the CRG Loan on Synergy’s behalf” on September 1, 2017, and “chose to discuss certain terms of the CRG Loan, but not others, demonstrating that he possessed actual knowledge of the terms of the Loan.”²⁸ (ECF No. 105 at ¶¶ 124-25.) They also claim that he was aware that “Synergy’s \$117.8 million cash position was below the requirements of the Cash Condition Precedent,” that “Synergy’s \$61.3 million cash burn rate vastly exceeded its revenues,” that “Synergy’s go-it-alone commercialization strategy for Trulance required the Company to incur substantial amounts of SG&A and other expenses going forward,” and that “the \$128 million Cash Condition Precedent all but necessitated a dilutive equity offering.” (*Id.* at ¶ 128.) In support of this allegation, they cite certifications that Gemignani signed, in which he attested that he reviewed Synergy’s Form 10-Qs.²⁹ (*Id.*) While

²⁸ The plaintiffs also allege that “the Loan required . . . a resolution of the Synergy Board, of which Defendant Jacob was a member,” and that “the entire Board, including Defendant Jacob, had to have . . . approved [the CRG Loan] by official resolution.” (ECF No. 105 at ¶ 124.) However, they do not “specifically identify” any document containing the terms of the CRG Loan that Jacob actually reviewed or to which he had access, or provide any details about when he received it or its contents. *Teamsters*, 531 F.3d at 196. The plaintiffs further allege that Jacob signed a Form 8-K “disclosing entry into the Loan” and “discuss[ing] various covenants and requirements contained in the Loan, but omits mention of the Cash Condition Precedent.” (ECF No. 105 at ¶ 127.) The plaintiffs cannot argue that Jacob was aware of the Cash Condition Precedent because he signed a document that, as they allege, *omitted* that loan provision. The plaintiffs’ conclusory allegation that Hamilton “had access to the entire CRG Loan agreement,” without more, is clearly inadequate. (*Id.* at ¶ 124.)

²⁹ The plaintiffs also claim that Gemignani was “aware of and/or had access to the facts of Synergy’s \$61.3 million cash burn rate and \$2.5 million average Trulance revenues” because he made qualitative comments regarding Synergy’s cash burn rate and when the company expected to be “cash flow breakeven.” (ECF No. 105 at ¶ 129.) However, the plaintiffs make no allegations about what data Gemignani reviewed that formed the basis for these comments.

the certifications may show that Gemignani reviewed or had access to Synergy’s Form 10-Qs, the plaintiffs do not specify which reports or documents contained each of the purported contrary facts.³⁰ Accordingly, the plaintiffs have not sufficiently pled conscious misbehavior or recklessness.

The plaintiffs make general claims about what the defendants must have known based on their industry experience. They allege that defendants were “highly educated, trained, and experienced in . . . financing and were therefore well-aware that their statements regarding . . . the CRG Loan were false and/or misleading and omitted material information.” (*Id.* at ¶ 131.) Specifically, Gemignani—Synergy’s Chief Financial Officer—has “served in executive financial and operational roles with multiple companies.”³¹ (*Id.* at ¶ 134.) However, “generalized allegations about the Individual Defendants’ ‘educational background’ and ‘extensive experience’ in the [relevant] industry do not raise an inference” of scienter.³² *Bd. of Trs. of City of Ft. Lauderdale Gen. Emps.’ Ret. Sys. v. Mechel OAO*, 811 F. Supp. 2d 853, 873 (S.D.N.Y. 2011), *aff’d sub nom. Frederick v. Mechel OAO*, 475 F. App’x 353 (2d Cir. 2012).

The plaintiffs also claim that the “suspicious timing of Jacob’s sudden resignation” on December 13, 2017—a month after Synergy announced the secondary offering—“suggests he

³⁰ The plaintiffs’ allegation that Jacob and Gemignani “signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (‘SOX’)” in connection with Synergy’s SEC filings (*id.* at ¶¶ 145-46), is similarly insufficient. See *Plumbers & Pipefitters Nat. Pension Fund v. Orthofix Int’l N.V.*, 89 F. Supp. 3d 602, 615 (S.D.N.Y. 2015) (“The plaintiff cannot raise an inference of fraudulent intent based on the signing of a certification without alleging any facts to show a concomitant awareness of or recklessness to the materially misleading nature of the statements.”).

³¹ The plaintiffs do not allege that Jacob or Hamilton has any relevant experience in “financing.” (ECF No. 105 at ¶¶ 133, 136.)

³² Similarly, the plaintiffs’ allegation that the defendants, “as senior executives, were in such positions at the Company to access all material, non-public information concerning the CRG Loan” (ECF No. 105 at ¶ 148), is insufficient because “accusations founded on nothing more than a defendant’s corporate position are entitled to no weight.” *Fogel v. Wal-Mart de Mexico SAB de CV*, No. 13-CV-2282, 2017 WL 751155, at *16 (S.D.N.Y. Feb. 27, 2017) (quoting *Strougo v. Barclays PLC*, 105 F. Supp. 3d 330, 350 (S.D.N.Y. 2015)).

was aware of and/or had access to information showing that . . . statements regarding the CRG Loan were false and/or misleading and omitted material information.” (ECF No. 105 at ¶ 147.) But Jacob did not resign from the company; he assumed the position of Executive Chairman of Synergy’s Board of Directors. (ECF No. 110-22 at 4.)³³ For this reason, none of the cases the plaintiffs cite are on point. *See generally In re OSG Sec. Litig.*, 12 F. Supp. 3d 622 (S.D.N.Y. 2014) (no indication that resignations were followed by appointments to another company position); *Plumbers & Pipefitters Nat’l Pension Fund v. Orthofix Int’l N.V.*, 89 F. Supp. 3d 602 (S.D.N.Y. 2015) (same); *In re BISYS Sec. Litig.*, 397 F. Supp. 2d 430 (S.D.N.Y. 2005) (same).

Last, the plaintiffs allege that “the CRG Loan was integral to Synergy’s strategy for the commercialization of Trulance” because it “provid[ed] the financing needed to fund such commercialization efforts through 2019;” therefore, the plaintiffs argue, the defendants “were aware of the facts that were omitted and misrepresented by them.” (ECF No. 105 at ¶¶ 149-50.) To the extent the plaintiffs are making “core operations” allegations,³⁴ those allegations “constitute a supplementary, but not an independent, means to plead scienter.” *Cheng*, No. 19-CV-8204, 2021 WL 3077469, at *10; *see Frederick*, 475 F. App’x at 356 (“[W]e have not yet expressly addressed whether, and in what form, the ‘core operations’ doctrine survives as a viable theory of scienter.”). Since the plaintiffs have not pled scienter, their core operations allegations also fail. Accordingly, the plaintiffs have not alleged facts establishing a strong inference of scienter.

³³ The plaintiffs cite this Form 8-K in the SAC. (ECF No. 105 at ¶ 147.)

³⁴ The “core operations” doctrine provides that “if a plaintiff can plead that a defendant made false or misleading statements when contradictory facts of critical importance to the company either were apparent, or should have been apparent, an inference arises that high-level officers and directors had knowledge of those facts by virtue of their positions with the company.” *In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 489 (S.D.N.Y. 2004) (citing *Cosmas v. Hassett*, 886 F.2d 8, 13 (2d Cir. 1989)).

II. Section 20(a) Claim

The plaintiffs also allege “controlling person liability” against the defendants pursuant to Section 20(a), 15 U.S.C. § 78t(a). *See Levy v. Maggiore*, 48 F. Supp. 3d 428, 439-40 (E.D.N.Y. 2014) (citations omitted). Under Section 20(a), “every person who, directly or indirectly, controls any person directly liable under the Securities Exchange Act” is also liable. *Levy*, 48 F. Supp. 3d, at 439-40 (citing *Steginsky v. Xcelera Inc.*, 741 F.3d 365, 371 (2d Cir. 2014)) (internal quotation marks and alterations omitted). A party cannot be held both primarily and secondarily liable for Exchange Act violations, but a plaintiff may allege both as alternative theories of liability at the pleading stage. *Id.* at 440 (citing *Szulik v. Tagliaferri*, 966 F. Supp. 2d 339, 368-69 (S.D.N.Y. 2013); *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 77 (2d Cir. 2001); *Suez Equity Invs., L.P. v. Toronto-Dominion Bank*, 250 F.3d 87, 101 (2d Cir. 2001)).

Since the plaintiffs have not identified any actionable misstatements or adequately alleged scienter or loss causation, they have not adequately pled a Section 10(b) claim. Therefore, their Section 20(a) control person claim fails as well, as control person liability under Section 20(a) depends on a primary violation of Section 10(b). Accordingly, I dismiss the plaintiffs’ Section 20(a) claim.

CONCLUSION

The defendants’ motion to dismiss the complaint is granted.³⁵

³⁵ The plaintiffs have amended their complaint twice, and have not asked to file a third amended complaint. *Ellis v. Chao*, 336 F.3d 114, 127 (2d Cir. 2003) (“[I]t is well established that leave to amend a complaint need not be granted when amendment would be futile.”). The plaintiffs’ motion to partially lift the automatic discovery stay (ECF No. 115) is denied as moot.

SO ORDERED.

s/Ann M. Donnelly

ANN M. DONNELLY
United States District Judge

Dated: Brooklyn, New York
September 30, 2021